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Erbitux in preoperative chemo-radiotherapy followed by excisional surgery

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 29/07/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-giving-biological-therapy-as-well-as-combined-chemotherapy-and-radiotherapy-before-surgery-cancer-back-passage-xerxes

Contact information

Type(s)
Scientific

Contact name
Dr Wendy Wood

Contact details
CR UK and UCL Cancer Trials Centre
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ

Additional identifiers

EudraCT/CTIS number
2004-001926-26

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1680

Study information

Scientific Title
Examining the role of Early Neoadjuvant and Synchronous Erbitux in Preoperative Chemo-Radiotherapy using Xeloda followed by Excisional Surgery

Acronym
XERXES

Study objectives
This is a multicentre pilot trial to establish the role of intravenous cetuximab when added to a schedule of capecitabine plus pelvic radiation in patients who have locally advanced primary rectal cancers. Cetuximab will be given by intravenous (iv) infusion at a loading dose of 400 mg /m^2 and subsequently at 250 mg/m^2 weekly. Capecitabine will be taken twice daily (bd) by mouth at 825 mg/m^2 bd on Monday - Friday each week for 5 weeks during radiotherapy.

Toxicity during treatment will be evaluated and the frequency of toxicity-led dose reductions and delays will be monitored closely. The aim is to determine the toxicity for this combined modality schedule, and a preliminary assessment of efficacy for future evaluation in a randomised controlled trial. Whilst efficacy data are always limited in a small feasibility study, radiological +/- histopathological assessment in the surgical specimen will be used to provide preliminary measures of efficacy in this patient cohort.

This study offers the opportunity to obtain biopsy material on chemo-naïve patients with rectal cancer and to examine the histological and downstream effects of single agent cetuximab.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley Research Ethics Committee, 06/04/2005, ref: 05/S0501/49

Study design
Multicentre non-randomized interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Rectum

Interventions
All patients receive the following:
Radiotherapy: planned total dose of 45 Gy in 25 fractions using a three or four field plan in 33 days.
Capecitabine: 825 mg/m^2 twice daily orally (Mon - Fri) over 5 weeks during radiotherapy.
Radical Surgery: to be undertaken ideally 6 - 10 weeks following completion of chemoradiation.

Group 1: the first 12 patients will receive cetuximab 400 mg/m2 in a short iv infusion as a starting dose then a weekly dose of 250 mg/m2 for 4 weeks prior to chemoradiation (days 3, 10, 17, 24).

Group 2: the subsequent 48 patients will be randomised into:
Arm A: Chemoradiotherapy only (no cetuximab)
Arm B: Cetuximab at the above doses for 4 weeks prior to chemoradiation and 5 weeks after (not during)

Study entry: registration only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cetuximab, capecitabine

Primary outcome measure
1. Acute Toxicity (Grade 3 or above in defined DLT)
2. Compliance with the planned dose of radiotherapy

Assessed after the patient has had surgery.

Secondary outcome measures
1. Histopathological downstaging (yPT0,T1,T2 N0)
2. Histologically confirmed (R0) resection

Assessed after the patient has had surgery.

Overall study start date
06/12/2005

Completion date
01/04/2014

Eligibility

Key inclusion criteria

1. Adenocarcinoma of the rectum (within 15 cm of anal verge)
2. Tumour tissue available for testing of epidermal growth factor receptor (EGFR) status
3. Indication for pre-operative chemoradiotherapy with R0 resection unlikely
4. Fit for chemotherapy
5. Written informed consent for both treatment and biopsies
6. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 60

Total final enrolment
22

Key exclusion criteria
1. Previous radiotherapy to the pelvis
2. Previous pelvic resectional surgery (cystectomy, hysterectomy)
3. Previous chemotherapy or radiation for rectal cancer
4. Previous chemotherapy for metastatic disease
5. Patients who have very significant small bowel delineated within the radiation fields
6. Currently enrolled in any other treatment trial

Date of first enrolment
06/12/2005

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CR UK and UCL Cancer Trials Centre
London

United Kingdom
W1T 4TJ

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Ltd (MSD) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			16/05/2019	No	No
Plain English results			29/07/2024	No	Yes